

KD43612

FEB - 9 2005

GE Healthcare

December 23, 2004

31

Traditional 510(k) for Orthopantomograph®OP200, OP200D and Orthoceph®OC200, OC200D

Appendix 7: 510(k) Summary

General Electric Company
Instrumentarium Corp.
Imaging Division

Nahkelantie 160, P.O.Box 20
FIN-04301 Tuusula, Finland

T +358 10 394 6500
F +358 10 394 6501



Instrumentarium Corporation, FIN-00031 INSTRUMENTARIUM, Trade Reg. No.12.570, VAT FI01092226

Traditional 510(k) for Orthopantomograph®OP200, OP200D and Orthoceph®OC200, OC200D

510(k) Summary

Manufacturer

Instrumentarium Corp. Imaging division
- Now Part of GE Healthcare
P.O.Box 20 (Street address: Nahkelantie 160)
FIN-04301-Tuusula, Finland

Phone: +358 10 394 6500

Fax: +358 10 394 6501

Contact Person: Kaija Jokela

United States Sales Representative (U.S. Designated agent)

Instrumentarium Imaging Inc.
300 West Edgerton Avenue
Milwaukee, Wisconsin 53207
Contact Person: Mark Mason

Phone: 414-747-1030

Fax: 414-481-8665

Product, Classification name

Orthopantomograph® OP200, OP200D, Orthoceph®OC200, OC200D
(Dental panoramic x-ray equipment with cephalostat)

Extraoral source X-ray system/ EHD

Regulation number: 872.1800

Substantial Equivalence:

We consider these products are similar in design, composition and function to the following devices introduced into commercial distribution after May 28, 1976:

Orthopantomograph®OP100D	#K992385
Orthoceph®OC100D	#K001439
Orthopantomograph® OP100 and Orthoceph® OC100	#K973642

General Electric Company

Instrumentarium Corp.

Imaging Division

Nahkelantie 160, P.O.Box 20

FIN-04301 Tuusula, Finland

T +358 10 394 6500

F +358 10 394 6501



Traditional 510(k) for Orthopantomograph® OP200, OP200D and Orthoceph® OC200, OC200D

The comparison of characteristics supports substantial equivalence. OP200/OC200/OP200D/OC200D integrates the features of the predicate devices to the new platform.

Description:

Panoramic X-ray devices Orthopantomograph® OP200, OP200 D and cephalometric options Orthoceph® OC200, OC200 D are the next generation in the Orthopantomograph® and Orthoceph® family. In the case of OP200 and OC200 devices, the image is captured to the film whilst OP200 D and OC200 D offer digital imaging.

The units include patented V-shaped X-ray beam that adapts to the bone density and structure of the human anatomy. In the OP200 D and OC200 D the imaging geometry remains the same as in film-based imaging (OP200, OC200), thereby enabling comparison to earlier film-based studies.

The patient positioning is easy and accurate thanks to motorized movements and three light lines for correct positioning of the patient's head. The patient's midsagittal view can be seen in a panoramic mirror and the electrically locked rigid forehead support is used to stabilize the head. Patient positioning can be performed on the left or right side.

When OP200 or OC200 units are equipped with CR option they have bigger 24x30cm cassette holder in panoramic side. Normal cassette holder size is 15x30cm. With this bigger 24x30cm cassette holder CR imaging plates can be used.

Optional Ortho ID film marking system can be used to store exposure parameters, patient and clinic information to films. Ortho ID is connected to OP200 or OC200 film units.

Equipments are designed to be field upgradeable. This means that for example basic OP200 film unit can be field upgraded to OC200 (cephalometric imaging) or OP200 D digital or OC200 D digital. All different options like OT, CR, etc. can be field upgraded afterwards.

Intended use:

Orthopantomograph® OP200 (film unit) and OP200 D (digital unit) devices are intended to be used for producing X-ray radiographs of dentition, TM-joints and other oral structures. The units are capable of taking panoramic, TM-joint and maxillary sinus radiographs from patients. When the units are equipped with cephalometric option Orthoceph® OC200 (film unit) or OC200 D (digital unit) units can be used for cephalometric radiography and examinations related

General Electric Company

Instrumentarium Corp.

Imaging Division

Nahkelaantie 160, P.O.Box 20

FIN-04301 Tuusula, Finland

T +358 10 394 6500

F +358 10 394 6501



Traditional 510(k) for Orthopantomograph®OP200, OP200D and Orthoceph®OC200, OC200D

thereto. OP200 or OC200 units can also be equipped with Ortho Trans (OT) option, which is capable of taking both cross and longitudinal slices of region of interest. Ortho Trans uses linear tomography imaging principle.

General Electric Company

Instrumentarium Corp.

Imaging Division

Nahkelantie 160, P.O.Box 20

FIN-04301 Tuusula, Finland

T +358 10 394 6500

F +358 10 394 6501



Instrumentarium Corporation, FIN-00031 INSTRUMENTARIUM, Trade Reg. No.12.570, VAT FI01092226



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

GE Healthcare
% Mr. Mark Mason
US Agent
Instrumentarium Imaging, Inc.
300 West Edgerton Avenue
MILWAUKEE WI 53207

Re: K043612
Trade/Device Name: Orthopantomograph® OP200, OP2001
Orthoceph® OC200, OC200D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: December 23, 2005
Received: January 13, 2005

Dear Mr. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

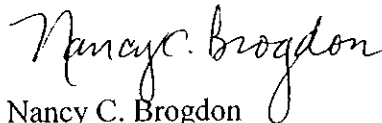
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Traditional 510(k) for Orthopantomograph®OP200, OP200D and Orthoceph®OC200, OC200D

Indications for Use

510(k) Number (if known): K 043612

Device Name: Orthopantomograph®OP200, OP200D, Orthoceph®OC200, OC200D

Indications for Use:

Orthopantomograph® OP200 (film unit) and OP200 D (digital unit) devices are intended to be used for producing X-ray radiographs of dentition, TM-joints and other oral structures. The units are capable of taking panoramic, TM-joint and maxillary sinus radiographs from patients. When the units are equipped with cephalometric option Orthoceph® OC200 (film unit) or OC200 D (digital unit) units can be used for cephalometric radiography and examinations related thereto. OP200 or OC200 units can also be equipped with Ortho Trans (OT) option, which is capable of taking both cross and longitudinal slices of region of interest. Ortho Trans uses linear tomography imaging principle.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043612

General Electric Company
Instrumentarium Corp.
Imaging Division
Nahkelantie 160, P.O.Box 20
FIN-04301 Tuusula, Finland

T +358 10 394 6500
F +358 10 394 6501

